



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0904; FRL-9912-92]

Bifenazate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bifenazate in or on multiple commodities which are identified and discussed later in this document including tolerances with regional restrictions for timothy hay and timothy forage. In addition, this regulation removes existing tolerances on “fruit, pome, group 11” “vegetable, fruiting, group 8” and existing time-limited tolerances for “timothy, forage” and “timothy, hay” that are superseded by this action. The Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2010-0904, is available at <http://www.regulations.gov> or at the Office of Pesticide

Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0904 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0904, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of Wednesday, July 6, 2011 (76 FR 39358) (FRL-8875-6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP1E7847) by the Interregional Research Project Number 4 (IR-4), IR-4 Project Headquarters, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.572 be amended by establishing tolerances for residues of bifenazate: Hydrazine carboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl)-methylethyl ester in or on fruit, pome, group 11-10 at 0.75 parts per million (ppm); herb, subgroup 19A dried leaves, except chervil, dried and chive, dried, at 140 ppm; herb, subgroup 19A, fresh leaves at 30 ppm; timothy, forage at 140 ppm; timothy, hay at 120 ppm; and vegetable, fruiting, group 8-10 at 2.0 ppm. That document referenced a summary of the petition prepared by Chemtura Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance level and corrected the commodity definition for certain commodities, and revised the tolerance expression for bifenazate. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for bifenazate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with bifenazate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Bifenazate has low acute toxicity for the oral, dermal and inhalation routes of exposure. For subchronic oral exposures, the dog is the most sensitive species. For chronic oral exposures, the dog and the rat are equally sensitive.

Subchronic and chronic studies in rats and dogs indicate that the liver and hematopoietic system (spleen and bone marrow with associated hematological findings) are the primary target organs in these species. Additional toxicity was seen in the kidney (dogs following chronic exposure) and adrenal cortex (male rats following subchronic exposure). Decreases in body weight, body-weight gain, and food consumption were also associated with liver and hematopoietic system toxicity in several studies.

In the rat developmental toxicity study, the maternal effects consisted of clinical signs of toxicity, decreased body weight and body-weight gains, and reduced food consumption at the mid-dose. Increases in early fetal resorptions occurred at the same doses that caused maternal toxicity. In the rabbit developmental toxicity study, there were no maternal or developmental effects up to the highest dose tested (HDT). In the 2-generation rat reproduction study, the parental effects occurred at the mid-dose and consisted of decreased body weight and body-weight gains. There were no reproductive or offspring effects up to the HDT.

In the acute neurotoxicity study, treatment related effects were seen only at the HDT, and consisted of decreased motor activity (rearing in females; center time in both sexes). In the subchronic neurotoxicity study, effects were also only seen at the HDT (34.5

milligrams/kilogram/day (mg/kg/day) and consisted of decreased landing foot splay (males), decreased fore- and hindlimb grip strength (males), decreased motor activity measurements consisting of center times (females) and rearing activity (both sexes). The level of concern (LOC) for neurotoxicity in the bifentazate database is low however because;

- The observed effects are well characterized;
- They occur only at the highest doses tested; and
- They are protected for by the studies used in the endpoint selection.

There were no observed toxicological effects in the immunotoxicity study up to the HDT.

In the mouse carcinogenicity study, males and females were tested up to 225 ppm and 175 ppm, respectively, which elicited decreased body weight and body-weight gains in females. In male mice, there was an increase in the incidence of liver adenomas only, which was not considered statistically significant by pair-wise comparison. There also was no progression of the adenomas to carcinomas in males in this study. A full battery of mutagenicity studies were negative for mutagenic or clastogenic activity. Bifentazate is classified as “not likely” to be carcinogenic to humans.

Specific information on the studies received and the nature of the adverse effects caused by bifentazate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document, “Bifentazate. Human-Health Risk Assessment. Section 3 Registration Request to Add New Uses on Timothy Forage and Hay; Herb, Subgroup 19A; and to Expand Existing Uses on Pome Fruit, Group 11, and Fruiting Vegetables, Group 8”, dated May 15, 2014, page 40 in docket ID number EPA-HQ-OPP-2010-0904.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment.

PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for bifenthrin used for human risk assessment is shown in the Table of this unit.

Table -- Summary of Toxicological Doses and Endpoints for Bifenthrin for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects

Acute dietary (Females 13-49 years of age)	NOAEL = 10 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Acute RfD = 0.1 mg/kg/day aPAD = 0.1 mg/kg/day	Prenatal Developmental Toxicity – Rats Developmental LOAEL = 100 mg/kg/day based on clinical signs, decreased body weight and food consumption during the dosing period.
Acute dietary (General population including infants and children)	NOAEL = 600 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Acute RfD = 6 mg/kg/day aPAD = 6 mg/kg/day	Acute Neurotoxicity Screening Battery - Rats LOAEL = 2,000 mg/kg/day based on decreased motor activity (rearing in females).
Chronic dietary (All populations)	NOAEL = 1.0 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x Co-critical Study NOAEL = 1.5 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Chronic RfD = 0.01 mg/kg/day cPAD = 0.01 mg/kg/day	Chronic toxicity - Dogs LOAEL = 8.9/10.4 mg/kg/day (M/F) based on changes in hematological and clinical chemistry parameters, and histopathology in bone marrow, liver, and kidney in the one-year dog feeding study. Carcinogenicity Study-Mouse LOAEL = 15.4 (M) mg/kg/day based on hematology parameters and possibly kidney weights.

Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months)	NOAEL= 0.9 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Residential LOC for MOE = 100	90-Day Subchronic - Dogs LOAEL = 10.4 mg/kg/day based on based upon changes in hematological parameters in both sexes, increased bilirubin in the urine in males, increased absolute and relative liver weight in females and liver histopathological effects in both sexes.
Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Dermal study LOAEL = 80 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Residential LOC for MOE = 100	21-Day Dermal toxicity – Rat LOAEL = 400 mg/kg/day based on decreased body weight in females, decreased food consumption in both sexes, increased urinary ketones, increased urinary protein, increased urinary specific gravity, and decreased urinary volume in both sexes, and increased incidence of extra medullary hematopoiesis in the spleen in both sexes.

Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months)	Rat NOAEL= 0.03 mg/L <hr/> HEC = 0.0009 mg/L HED = 0.14mg/kg bw/day UF _A = 3x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 30	28-Day Inhalation Toxicity - Rat LOAEL = 0.075 mg/L (M/F) on dried red material around the nose in females, lower body weights and body-weight gains, decreased food consumption, decreased heart and thymus weights in females, increased incidences of mild brown pigmentation of the spleen, and minimal to mild degeneration of the olfactory epithelium within nasal levels III, IV, and V.
Cancer (Oral, dermal, inhalation)	Bifenazate is classified as "not likely to be a human carcinogen".		

Point of departure (POD) = a data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. Reference Dose = RfD. Male/Female = (M/F). FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). Human Equivalent Concentration (HEC) where HEC Calculations for Short- and Intermediate-term Residential Exposure: Assume residents will be exposed for 24 hrs/day and 7 days/week: $HEC = NOAEL_{study} * (daily\ duration\ of\ exposure_{animal} / daily\ duration\ of\ exposure_{human}) * (days/week\ of\ exposure_{animal} / days/week\ of\ exposure_{human}) * RDDR$

- $HEC = 0.03\ mg/L * (6/24) * (5/7) * 0.175 = 0.00094\ mg/L$.

Human Equivalent Dose (HED). HED's route-to-route extrapolation converts human and animal values from mg/L concentrations to mg/kg oral-equivalent doses. The equation uses a single conversion factor to account for default body weights and respiratory volumes. An activity factor is used to account for increased exposure resulting from increased respiration. Using the HEC calculated (based upon terminal airway inflammation in males), a conversion of the inhalation concentration to a dose (mg/L to mg/kg/day) was conducted as follows:

- Human-Equivalent Dose (HED, mg/kg/day) = Dose (systemic HEC value, mg/L) x A x CF (L/hr/kg) x D (hours) x AF = mg/kg

Where: A= absorption: ratio of deposition and absorption in respiratory tract compared to absorption by the oral route. CF = conversion Factor; a L/hr/kg factor which accounts for respiratory volume and body weight for a given species and strain. D = duration; duration of daily animal or human exposure (hours). AF = activity Factor; animal default is 1. The residential human equivalent dose for bifenthrin is calculated as follows:

- Residential HED: (0.0009 mg/L) x 1 x 6 x 8 x 1 = 0.135 mg/kg/day

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to bifenthrin, EPA considered exposure under the petitioned-for tolerances as well as all existing bifenthrin tolerances in 40 CFR 180.572. EPA assessed dietary exposures from bifenthrin in food as follows:

i. *Acute exposure.* In conducting the acute dietary exposure assessment EPA used the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID, ver. 3.16), which incorporates consumption information from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008.

As to residue levels in food, the acute analysis for the general population, including infants and children, was unrefined and used tolerance-level residues and 100 PCT. The acute analysis for females 13 to 49 years old was highly refined and incorporated data from the USDA's Pesticide Data Program (PDP), crop field trial data, and PCT estimates. DEEM (ver. 7.81) default processing factors were assumed for all commodities excluding apple juice, grape juice, and wine/sherry. The processing factors for these commodities were reduced to 1.0, based on data from processing studies.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID, ver. 3-16 which incorporates consumption information from the USDA NHANES/WWEIA; 2003-2008. As to residue levels in food, the chronic dietary exposure analysis for all population subgroups was partially refined and used tolerance-level residues and PCT estimates. DEEM default processing factors were assumed for all commodities excluding apple juice, grape juice, and wine/sherry. The processing factors for these commodities were reduced to 1.0 based on data from processing studies.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has classified bifenazate as “not likely” to be a human carcinogen. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

Maximum PCT estimates were used in the acute dietary risk assessment: almonds: 10%; apples: 5%; apricots: 10%; beans, green: 2.5%; caneberries: 30%; cantaloupes: 2.5%; cherries: 5%; cucumbers: 5%; grapefruit: 5%; grapes: 20%; nectarines: 10%; oranges: 2.5%; peaches: 20%; pears: 30%; pecans: 2.5%; peppers: 10%; pistachios: 2.5%; plums/prunes: 20%; potatoes: 5%; pumpkins: 5%; squash: 2.5%; strawberries: 65%; tomatoes: 10%; walnuts: 5%; and watermelon: 2.5%.

The following average PCT estimates were used in the chronic dietary risk assessment: almonds: 5%; apples: 5%; apricots: 5%; beans, green: 1%; caneberries: 25%; cantaloupes: 1%; cherries: 2.5%; cucumbers: 2.5%; grapefruit: 5%; grapes: 10%; nectarines: 5%; oranges: 1%; peaches: 10%; pears: 15%; pecans: 1%; peppers: 5%; pistachios: 2.5%; plums/prunes: 5%; potatoes: 5%; pumpkins: 2.5%; squash: 1%; strawberries: 45%; tomatoes: 5%; walnuts: 2.5%; and watermelon: 1%.

In most cases, EPA uses available data from USDA/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the

chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which bifenthrin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for bifenthrin in drinking

water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of bifentazate. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) model and the dry bean application scenario (highest registered/proposed use rate) and the Screening Concentrations in Ground Water (SCI-GROW) model, the estimated drinking water concentrations (EDWCs) of bifentazate acute exposures are estimated to be 37.3 ppb for surface water and 0.014 ppb for ground water.

For chronic exposures for non-cancer assessments are estimated to be 11.2 ppb for surface water and 0.014 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 37.3 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 11.2 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Bifentazate is currently registered for the following uses that could result in residential exposures: Ornamental plants, including bedding plants, flowering plants, foliage plants, bulb

crops perennials, trees, and shrubs. EPA assessed residential exposure using the following assumptions: There is a potential for short-term dermal and inhalation exposures by homeowners applying bifenazate. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners.

The residential handler exposure assessment estimates dermal and inhalation exposures for individuals using bifenazate on residential ornamentals. The quantitative exposure/risk assessment developed for residential handlers is based on the following scenarios:

- i. Mixing/loading/applying liquids with manually-pressurized handwand,
- ii. Mixing/loading/applying liquids with hose-end sprayer,
- iii. Mixing/loading/applying liquids with backpack, and
- iv. Mixing/loading/applying liquids with sprinkler can.

Unit exposure values and estimates for area treated were taken from the 2012 Residential SOPs: Gardens and Trees. An aggregate risk index (ARI) was used since the LOCs for dermal exposure (100) and inhalation exposure (30) are different. The target ARI is 1; therefore, ARIs of less than 1 result in risk estimates of concern. The ARI was calculated as follows.

- *Aggregate Risk Index (ARI) = $1 \div [(Dermal\ LOC \div Dermal\ MOE) + (Inhalation\ LOC \div Inhalation\ MOE)]$*

Short-term risk estimates for residential handlers are greatest for exposure scenarios “hose-end sprayer” and “backpack” resulting in ARIs of 80 and 66, respectively. Short-term dermal and inhalation risk estimates to residential handlers do not exceed EPA’s LOC for all scenarios. All the ARIs are above 1 and do not exceed the Agency’s LOC for all scenarios.

Short-term dermal exposure and risk from residential post-application have been assessed for bifenazate under the following scenarios, routes of exposure and lifestyles:

- Gardens and Trees: adults (dermal) and children 6 to less than or equal 11 years old (dermal).

These lifestyles are not the only lifestyles that could be potentially exposed for these post-application scenarios; however, the assessment of these lifestyles is health protective for the exposures and risks for any other potentially exposed lifestyles. All adult and children dermal post-application risk estimates for exposure to treated trees and gardens are not of concern (MOEs ≥ 100). Details of assumptions and factors the Agency applied in residential and residential post-application exposure assessments are detailed in the 2012 Residential SOPs at <http://www.epa.gov/pesticides/science/residential-exposure-sop.html>.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found bifenazate to share a common mechanism of toxicity with any other substances, and bifenazate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that

bifenazate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology database for bifenazate includes rat and rabbit developmental toxicity studies and a 2-generation reproduction toxicity study in rats. In the rat developmental toxicity study, the maternal effects consisted of clinical signs of toxicity, decreased body weight and body-weight gains, and reduced food consumption at the mid-dose. Increases in early fetal resorptions occurred at the same doses that caused maternal toxicity. In the rabbit developmental toxicity study, there were no maternal or developmental effects up to the HDT. In the 2-generation rat reproduction study, the parental effects occurred at the mid-dose and consisted of decreased body weight and body-weight gains. There were no reproductive or offspring effects up to the HDT.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

- i. The toxicity database for bifentazate is complete.
- ii. There is evidence of neurotoxicity in the bifentazate database. The level of concern for neurotoxic effects in children is low however because
 - The observed effects are well characterized;
 - They occur only at the highest doses tested; and
 - They are protected for by the studies used in the endpoint selection.
- iii. There is no evidence that bifentazate results in increased susceptibility in *in utero* rats or rabbits in the pre- or postnatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The exposure databases are sufficient to determine the nature and magnitude of the residue in food and water. For acute exposure for the general population and chronic exposure, the dietary exposure analyses are unlikely to underestimate exposure as they incorporated tolerance-level residues, 100 PCT for acute exposure, PCT for chronic exposure, and modeled drinking water estimates. For acute analysis for females 13 to 49 years, the dietary analysis is unlikely to underestimate exposure as PDP, crop field trial data, PCT estimates and modeled drinking water estimates were utilized.

EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to bifenazate in drinking water. The dietary food and drinking water exposure assessments will not underestimate the potential exposures for infants and children. The residential use (ornamentals) is not expected to result in post-application exposure to infants and children as well as incidental oral exposure of toddlers. The post-application exposure assessments are based upon the residential SOPs, which are based upon reasonable worst-case assumptions and are not expected to underestimate risk. These assessments will not underestimate the exposure and risks posed by bifenazate.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to bifenazate will occupy <1.9% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure. The acute dietary exposure estimates are not of concern to EPA (<100% aPAD) for the general U.S. population and all population subgroups

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to bifenazate from food and water will utilize 74% of the cPAD for children 1 to 2 years old the population group receiving the greatest

exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of bifenazate is not expected.

3. *Short- and intermediate-term risks.* Short- and intermediate-term aggregate exposures take into account short- and intermediate-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Bifenazate is currently registered for uses that could result in short- and intermediate- term residential exposures.

The short- and intermediate-term toxicological PODs for bifenazate are the same for each route of exposure. Therefore, for residential exposure scenarios, only short-term exposures were assessed, and are considered to be protective of intermediate-term exposure and risk.

It was appropriate to aggregate postapplication dermal exposures with dietary (food and water) exposures. The dermal postapplication exposure to gardens and ornamentals scenario is the residential exposure scenario with the greatest risk estimate for both adults and children $6 \leq 11$ years old; therefore, the exposure estimates for this scenario are protective of any other exposure scenarios.

For the adult and children $6 \leq 11$ years old short- and intermediate-term aggregate risk assessment, the MOE approach was used to estimate aggregate exposures as there are different PODs for oral and dermal routes of exposure but the LOC are the same. The chronic dietary exposure estimate for Adults 20-49 years old and Children 6-12 years old were used in the aggregate risk estimate for adults and children $6 \leq 11$ years old, respectively.

All of the adult and children 6 ≤ 11 years old chronic dietary + dermal aggregate risk estimates do not exceed EPA's LOC (MOEs ≥ 100).

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, bifenazate (classified as "not likely" to be a human carcinogen) is therefore not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to bifenazate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available to enforce the tolerance expression.

For plant commodities, high-performance liquid chromatography with oxidative coulometric electrochemical detector (HPLC/ELCD) Method UCC-D2341 is available as a primary enforcement method for the combined residues of bifenazate and its metabolite D3598. The method has been forwarded to the United States Food and Drug Administration (FDA) for inclusion in the Pesticides Analytical Manual, Volume II (PAM II). The limit of quantification (LOQ) and limit of detection (LOD) of Method UCC-D2341 are 0.01 and 0.005 ppm, respectively. In addition, a liquid chromatographic system with tandem mass spectrometers (LC-MS/MS) method (NCL ME 245) was recently submitted as a confirmatory method and has been forwarded to FDA.

For livestock commodities, HPLC methods with fluorescence detection or ELCD are available as primary methods for the enforcement of tolerances for residues of bifenazate and its regulated metabolites in livestock matrices. The methods have undergone a successful validation by the Agency and have been forwarded to FDA for inclusion in PAM II. In addition, the LC-MS/MS Method NCL ME 259 was recently submitted as a confirmatory method, and this method was also forwarded to FDA. The validated LOQ was 0.01 ppm for each analyte. The LOD was reported as 0.005 ppm.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are currently no established Codex MRLs for bifenazate in/on herbs, and timothy forage and hay. Codex MRLs are established for pome fruits (0.7 ppm), chili peppers (3 ppm),

sweet peppers (2 ppm) and tomato (0.5 ppm), but not for other members of Vegetable, fruiting, group 8 – 10.

The U.S. is establishing a tolerance for Vegetable, fruiting, group 8-10 at 4.0 ppm for residues of bifenazate (and its metabolite). There is an existing U.S. tolerance of 2 ppm for Vegetables, fruiting, crop, group 8. This tolerance was established in 2003 prior to the implementation of the Organization for Economic Co-Operation and Development (OECD) calculation procedures. In 2007 Codex established the MRLs for chili peppers, sweet peppers and tomato and relied on the U.S. field trial data. Codex chose not to establish a group tolerance for the fruiting vegetables but instead established separate Codex MRLs for tomato, peppers and chili peppers using the highest observed residue approach. The approach taken by Codex is not in line with how the U.S. establishes crop group tolerances. Further, using the OECD calculation procedures and based on data from bell and non-bell pepper studies conducted in the U.S., and tomato studies conducted in Canada and the U.S. results in the recommended tolerance of 4.0 ppm.

EPA is establishing the U.S. tolerance for residue in or on pome fruit at 0.7 ppm, in harmonization with the established Codex MRL.

C. Revisions to Petitioned-For Tolerances

After reviewing supporting data and information, EPA modified certain elements of the petition as proposed in the notice of filing, as follows:

1. EPA corrected the proposed commodity definitions, “Herb, subgroup 19A, fresh leaves” and “Herb, subgroup 19A, dried leaves, except chervil, dried and chive, dried” to read

“Herb subgroup 19A, except chervil and chive” to specify crop coverage and for accuracy and consistency in naming of commodities.

2. Using the OECD tolerance-calculation procedures, the Agency modified proposed tolerance levels for certain commodities as follows:

i. A proposed tolerance at 140 ppm for “Herb, subgroup 19A, dried leaves, except chervil, dried and chive, dried” was established for “Herb, subgroup 19A, except chervil and chive” at 300 ppm, and

ii. A proposed tolerance at 140 ppm on timothy, forage, was established at 200 ppm (tolerance with regional registrations), and a proposed tolerance of 120 ppm on timothy, hay, was established at 150 ppm (tolerance with regional registrations).

3. As petitioned-for, EPA is establishing tolerances with regional registrations for timothy, forage and timothy, hay for regional use in two counties, Eureka and Humboldt, in the State of Nevada. Applications of bifenthrin can only be made to timothy that is intended for use as horse feed. Livestock feedstuffs are not derived from the proposed crops of the subject petition, except for timothy. The Agency is removing existing time-limited tolerances established for bifenthrin under section 18 emergency exemptions for timothy, forage and timothy, hay at 50 ppm and 150 ppm, respectively, as they are superseded by this action.

4. As previously stated, the U.S. tolerance for Vegetable, fruiting, group 8-10 is being changed to 4.0 ppm. This is based the use of the OECD calculation procedures on data from bell and non-bell pepper studies conducted in the United States, and tomato studies conducted in Canada and the United States.

In addition, the Agency is revising the tolerance expressions for bifentazate tolerances in order to conform to current EPA policy as follows:

5. 40 CFR §180.572(a)(1) is revised to read as follows: Tolerances are established for residues of bifentazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified are to be determined by measuring only the sum of bifentazate and its metabolite, diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester, (calculated as the stoichiometric equivalent of bifentazate) in or on food commodities, and

6. The tolerance expression for 40 CFR §180.572(a)(2) is modified as follows:
Tolerances are established for residues of bifentazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl) hydrazinecarboxylate) including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified are to be determined by measuring only the sum of bifentazate and its metabolites diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester; 1,1'-biphenyl, 4-ol; and 1,1'-biphenyl, 4-oxysulfonic acid (calculated as the stoichiometric equivalent of bifentazate) in or on food commodities.

V. Conclusion

Therefore, tolerances are established for residues of bifentazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) including its metabolites and degradates, in or on Herb subgroup 19A, except chervil and chive at 300 ppm, Timothy, forage at 200 ppm, Timothy, hay at 150 ppm, Fruit, pome, group 11 - 10 at 0.7 ppm and Vegetable, fruiting, group 8 – 10 at 4.0 ppm. In addition, this regulation removes existing tolerances on “fruit, pome, group

11” “vegetable, fruiting, group 8” and existing time-limited tolerances for “timothy, forage” and “timothy, hay” that are superseded by this action.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct

effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 21, 2014.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.572 is amended as follows:

- a. Revise the introductory text in paragraph (a)(1);
- b. Alphabetically add commodities to the table in paragraph (a)(1);
- c. Remove from the table in paragraph (a)(1) the entries for “Fruit, pome, group 11” and “Vegetable, fruiting, group 8”;
- d. Revise the introductory text in paragraph (a)(2) ;
- e. Remove and reserve paragraph (b); and
- f. Add paragraph (c) to read as follows:

§ 180.572 Bifenazate; tolerance for residues.

(a) *General.* (1) Tolerances are established for residues of bifenazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified are to be determined by measuring only the sum of bifenazate and its metabolite, diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester, (calculated as the stoichiometric equivalent of bifenazate) in or on the following food commodities:

Commodity	Parts per million
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* * * *	* * *
Fruit, pome, group 11 - 10	0.7
* * * *	* * *
Herb, subgroup 19A, except chervil and chive	300
* * * *	* * *
Vegetable, fruiting, group 8 - 10	4.0
* * * *	* * *

(2) Tolerances are established for residues of bifentazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl) hydrazinecarboxylate) including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified are to be determined by measuring only the sum of bifentazate and its metabolites diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester; 1,1'-biphenyl, 4-ol; and 1,1'-biphenyl, 4-oxysulfonic acid (calculated as the stoichiometric equivalent of bifentazate) in or on the following food commodities:

* * * *

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in §180.1(l), are established for residues of bifentazate (1-methylethyl 2-(4-methoxy[1,1'-biphenyl]-3-yl)hydrazinecarboxylate) including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified are to be determined by measuring only the sum of bifentazate and its metabolite, diazinecarboxylic acid,

2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester, (calculated as the stoichiometric equivalent of bifenazate) in or on the following food commodities:

Commodity	Parts per million
Timothy, forage	200
Timothy, hay	150

* * * * *